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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,783	07/25/2003	Martin Friedlander	TSRI-900.1	5526

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EXAMINER

NGUYEN, QUANG

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,783

Applicant(s)

FRIEDLANDER ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-65 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-65 are pending in the present application, and they are subjected to the following restrictions.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group Restriction

- I. Claims 1-49 and 62-65, drawn to an isolated, mammalian bone marrow-derived lineage negative hematopoietic stem cell population comprising endothelial progenitor cells in which at least about 50% of the cells include the cell markers CD31 and c-kit; a method of isolating bone marrow-derived, lineage negative hematopoietic stem cells including endothelial progenitor cells; a method of enhancing retinal neovascularization in a mammal or a method of treating an ocular disease or a method of inducing neurotrophic rescue in a retina of a mammal suffering from a retinal degenerative disease using the same stem cell population, classified in class 424, subclass 93.1.
- II. Claims 50-61, drawn to a transfected lineage negative hematopoietic stem cell population comprising a mammalian, bone marrow-derived lineage negative hematopoietic stem cell population of the present invention transfected with a gene encoding a therapeutically useful peptide; and a method of inhibiting retinal angiogenesis in the eye of a patient in need of

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retinal angiogenesis inhibition or a method of delivering transgenes to the retinal vasculature of a patient using the same transfected stem cell population, classified in class 424, subclass 93.21.

The inventions are distinct, each from the other because of the following reasons:

The stem cell population of Group I is distinct from the transfected stem cell population of Group II. Unlike the stem cell population of Group I, the transfected stem cell population of Group II contains a gene encoding a therapeutically useful peptide. The methods of Groups I-II have different method steps, starting materials (e.g., stem cell population vs transfected stem cell population), different desired end-results (e.g., enhancing retinal neovascularization of claim 29 vs inhibiting retinal angiogenesis in claim 55) and they require different technical considerations for achieving the desired results. Additionally, the method of Group I does not require the transfected stem cell population of Group II, and vice versa.

Searching and examining the inventions of Groups I-II would impose a serious burden since a search for the invention of Group I would not necessarily reveal a transfected stem cell population of Group II, and a method of using the same transfected stem cell population and/or render the invention of Group II obvious. It would be unduly burdensome for the examiner to perform a complete search of the defined areas in both the patent and non-paten literature, and/or consider the patentability of all the inventions in a single application. Therefore, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Species Restriction

Should Applicants elect the invention of Group I, this application contains claims directed to the following patentably distinct species of an ocular disease of the claimed invention:

1. retinal degenerative disease; 2. retinal vascular degenerative disease; 3. ischemic retinopathy; 4. vascular hemorrhage; 5. vascular leakage; 6. choroidopathy; 7. age-related macular degeneration; 8. diabetic retinopathy; 9. presumed ocular histoplasmosis; 10. retinopathy of prematurity; 11. sickle cell anemia; and 12. retinitis pigmentosa.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, at least claims 32-38 are generic.

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Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

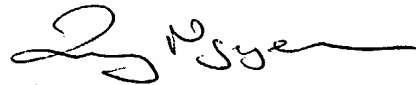
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Quang Nguyen, Ph.D.

A handwritten signature in black ink, appearing to read "Quang Nguyen", with a stylized flourish at the end.